Texas Department of Health
Bureau of Food and Drug Safety
Drugs and Medical Devices Division

Section

§229.461. Regulations to Restrict the Sale and Distribution of Dietary Supplements Containing Ephedrine.

The sale or distribution of any dietary supplement containing ephedrine group alkaloids is prohibited unless the product complies with the following requirements:

(1) the product contains no chemically synthesized ephedrine group alkaloids; and

(2) each batch shall be analyzed to ensure that it contains the amount of total ephedrine alkaloids listed on the product label.

§229.462. Product Labels for Dietary Supplements Containing Ephedrine.

(a) The product label must state: "This product has (insert amount in product) milligrams concentrated ephedrine group alkaloids per serving in the form of herbal extracts."

(b) The product label must use standardized nomenclature for the ephedrine ingredient such that the terms "ephedrine," "pseudoephedrine" or other ephedrine group alkaloid name is used when referring to the active ingredients in place of or in addition to the botanical name of the ephedrine group alkaloid.

(c) The product label must state the amount in milligrams of caffeine alkaloids and other ingredients per serving that have a known stimulant effect (eg. yohimbine).

(d) The product label must include a warning statement for the consumption of ephedrine group alkaloids that is conspicuously displayed on the label information panel in distinct contrast to

other printing or graphics, and must be at least 1/16 inch type.

(e) The warning on the product label must contain at a minimum the following information:

(1) WARNING: Not for use by individuals under the age of 18. Do not use if pregnant or nursing. Consult a physician or licensed qualified health care professional before using this product if you have, or have a family history of, heart disease, thyroid disease, diabetes, high blood pressure, recurrent headaches, depression or other psychiatric condition, glaucoma, difficulty in urinating, prostate enlargement, or seizure disorder, if you are using a monoamine oxidase inhibitor (MAOI) or any other dietary supplement, prescription drug or over-the-counter drug containing ephedrine, pseudoephedrine or phenylpropanolamine (ingredients found in certain allergy, asthma, cough/cold, and weight control products).

(2) Exceeding recommended serving may cause serious adverse health effects including heart attack and stroke.

(3) Discontinue use and call a physician or licensed qualified health care professional immediately if you experience rapid heartbeat, dizziness, severe headache, shortness of breath, or other similar symptoms.

(4) Individuals who consume caffeine with this product may experience serious adverse health effects.

(f) After September 1, 2001, the product label must include a toll-free number to permit consumers to report adverse effects. This toll-free number shall be 1-800-332-1088, which is the Food and Drug Administration's MedWatch medical product reporting program.

(g) All labeling, except that affixed to the product container, all prerecorded or scripted radio and television advertising, and all promotional literature must include the following warning: "This product" (optional: may use any specific reference to product) "has ephedrine group alkaloids in the form of herbal extracts" (optional: from ma huang or other named herb) "and may cause serious adverse health effects. Read the label and follow directions."

(h) After January 1, 2001, the product label must include a warning statement that indicates the sale to persons 17 years of age or younger is prohibited. This warning statement must be conspicuously displayed on the product label information panel or as an auxiliary label such as a sticker permanently affixed to the product container in distinct contrast to other printing or graphics, and must be at least 1/16 inch type.

§229.463. Advertising and Promotional Literature for Dietary Supplements Containing Ephedrine.

(a) All advertising and promotional literature must be reviewed and approved by the company responsible for the manufacture of the ephedrine containing dietary supplement product and must be submitted to the department in care of Drugs and Medical Devices Division, 1100 West 49th Street, Austin, Texas 78756.

(b) Companies that engage in direct marketing of ephedrine containing dietary supplement

products shall incorporate into contracts with distributors, franchisees, and/or independent contractors the following conditions:

(1) no claims about the product which have not been approved in writing by the company may be made;

(2) no medical claims may be made;

(3) distributors, franchisees, and/or independent contractors are required to direct consumers to read the product label prior to purchase or consumption;

(4) distributors, franchisees, and/or independent contractors are required to advise consumers under the care of a physician or with a chronic condition to consult with a physician prior to purchase of the product; and

(5) distributors, franchisees, and/or independent contractors shall refer any person who makes a complaint about side effects to a physician or licensed qualified health care professional.

(c) Companies that engage in direct marketing of ephedrine containing dietary supplement products shall effectively respond to distributors, franchisees, and/or independent contractors to prevent the distribution of unauthorized literature.

(d) Distributors, franchisees, and/or independent contractors shall be trained by companies that engage in direct marketing of ephedrine containing dietary supplement products to refer medical questions to a physician and will not be permitted to give medical advice.

(e) No claims shall be made for the indication of alteration of consciousness, euphoria, as a "legal" alternative for an illicit drug, or for any use of the product as a drug for the diagnosis, cure, mitigation, treatment, or prevention of any disease. To determine compliance with this requirement, the Texas Department of Health (department) may consider the following factors:

(1) the product packaging;

(2) the name and container labeling of the product; and

(3) advertising and promotional materials created by the company responsible for the manufacture or distribution of the product.

(f) Prior to any company distributing an ephedrine containing dietary supplement product in Texas, the product label shall be submitted to the Texas Poison Center Coordinating Committee, in care of Chief, Bureau of Epidemiology, Texas Department of Health, 1100 West 49th Street, Austin, Texas 78756.

§229.464. Regulations to Restrict the Sale and Distribution of Certain Drug Products Containing Ephedrine.

(a) Drug products containing single ingredient ephedrine, its salts, optical isomers or salts of optical isomers, are dangerous drugs as defined in the Health and Safety Code, Chapter 483, relating to Dangerous Drugs.

(b) Drug products that contain pseudoephedrine are exempt from the designation as dangerous drugs if the drug product is labeled in accordance with the U. S. Food and Drug Administration’s final monograph.

(c) Any drug product containing ephedrine, its salts, optical isomers or salts of optical isomers shall not be sold, distributed, introduced into commerce, manufactured, produced, packaged, exposed, offered, possessed or held for sale, dispensed or given away in this state except as dispensed upon the prescription of a licensed practitioner.

(d) The following formulations are exempt from the designation as dangerous drugs under subsection (a) of this section, and the dispensing restrictions under subsection (c) of this section:

(1) solid dosage forms that combine active ingredients must be in the following ranges for each recommended dose: ephedrine, its salts, optical isomers or salts of optical isomers not to exceed 12.5 milligrams (mg) combined with at least 200 mg guiafenesin; ephedrine, its salts, optical isomers or salts of optical isomers not to exceed 25 mg combined with at least 400 mg guiafenesin;

(2) liquid oral dosage forms that combine active ingredients in the following ranges for each 5 milliliter (ml) dose: dextromethorphan HBr (not more than 10 mg), chlorpheniramine maleate (not more than 2 mg), ephedrine HCl (not more than 5 mg), phenylephrine (not more than 5 mg), ammonium chloride (not more than 40 mg), ipecac fluidextract (not more than 0.005 ml);

(3) anorectal preparations containing less than 5.0% ephedrine;

(4) nasal decongestant preparations containing 0.5% or less ephedrine; and

(5) any ephedrine-containing drug product that is marketed pursuant to an approved new drug application under the Federal Food, Drug, and Cosmetic Act.